

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Goddard, et al.
Appl. No. : 10/063578
Filed : May 3, 2002
For : ANTIBODIES THAT BIND A PRO1158
POLYPEPTIDE
Examiner : Zachary C. Howard
Group Art Unit : 1646

DECLARATION UNDER 37 CFR §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We declare and state as follows:

1. We are the inventors of the invention claimed in the above-captioned patent application.
2. During the time period in which we participated in the events and activities described herein, we were employed by Genentech, Inc., the assignee of the above-captioned application.
3. All of the events and activities described herein were performed by us personally, or by others at our direction as part of our duties as employees of Genentech, Inc.
4. The subject matter and utility of the claimed invention in the above-captioned patent application was conceived prior and constructively reduced to practice in the U.S. prior to August 7, 2000 as described below.
5. Prior to August 7, 2000, I and/or my co-inventors conceived of the invention claimed in the above-captioned patent application. The nucleic acid of SEQ ID NO: 67 was initially identified as being of interest based upon the results obtained with an algorithm which identifies

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signal sequences. This algorithm identified an EST cluster in a database of EST sequences non-exclusively licensed from Incyte. The EST cluster sequence was then compared to a variety of EST databases and a consensus sequence, designated "DNA57248" was identified by Genentech prior to August 7, 2000. DNA57248 partially overlapped an Incyte clone designated EST Clone No. 2640776. Accordingly, Incyte EST Clone No. 2640776 was ordered from Incyte.

6. The complete sequence of the insert in Incyte Clone No. 2640776 was determined at Genentech prior to August 7, 2000 and designated DNA60625. DNA60625 is SEQ ID NO: 67 in the above-identified application. Genentech determined the complete sequence of SEQ ID NO: 67.

7. Incyte Clone No. 2640776 contained the entire sequence of SEQ ID NO: 67 within it. However, for Incyte Clone No. 2640776, Incyte had only determined the sequence of the nucleotides corresponding to nucleotides 1-200 of SEQ ID NO: 67. SEQ ID NO: 67 is 744 nucleotides in length, with a coding region extending from nucleotide 163 through nucleotide 531. Thus, in Incyte Clone 2640776, Incyte did not determine the complete sequence of SEQ ID NO: 67, the complete sequence of a nucleic acid encoding the polypeptide of SEQ ID NO: 68 and the corresponding amino acid sequence of SEQ ID NO: 68.

8. Prior to August 7, 2000, the idea of investigating several newly discovered DNA sequences for their relevance, including developing primers and cloning the DNA sequences of interest from normal and tumor tissues, was conceived. The sequences of SEQ ID NOs: 67 and 68 were first disclosed in U.S. Provisional Application 60/090246, filed June 22, 1998, in SEQ ID NO: 1 and Figure 1. Antibodies to said polypeptides sequence were also contemplated as disclosed in the provisional application. In addition, various utilities for the disclosed nucleic acids, polypeptides, and antibodies, including use as diagnostic agents, were also conceived prior to June 22, 1998, and included in the provisional application. Thus, conception of the invention claimed in the above-captioned patent application occurred prior to June 22, 1998.

9. After these initial experiments, we continued to produce primers, clone and sequence other DNA sequences. We then began to identify the expression levels of the cloned sequences, and created constructs for expression of the encoded proteins. PCR primers for use in the detection of DNA60625 expression were made on March 6, 2000 and expression analyses were performed thereafter. Exhibit A shows an experiment in which the primers were used to determine the expression level of DNA60625 in various tumor samples and their normal tissue counterparts. These gel data demonstrate that DNA60625 is more highly expressed in normal lung tissue than in lung tumor. These exhibits show diligence in reducing to practice following conception of the invention. Thus, we conceived of the present invention prior to August 7, 2000 and were diligent in reducing the invention to practice.

10. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true, and further that these

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statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: *Audrey Goddard* Date: *7/26/07*
Audrey Goddard

By: _____ Date: _____
J. Christopher Grimaldi

By: _____ Date: _____
Austin L. Gurney

By: _____ Date: _____
William I. Wood

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statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____
Audrey Goddard

By: _____
J. Christopher Grimaldi

By: _____
Austin L. Gurney

By: _____
William I. Wood

Date: _____

Date: 9/5/07

Date: _____

Date: _____

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By: _____
Audrey Goddard

Date: _____

By: _____
J. Christopher Grimaldi

Date: _____

By: _____
Austin L. Gurney

Date: 8/29/07

By: _____
William I. Wood

Date: _____

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Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

By: _____
Audrey Goddard

Date: _____

By: _____
J. Christopher Grimaldi

Date: _____

By: _____
Austin L. Gurney

Date: _____

By: William I. Wood
William I. Wood

Date: 9/21/07

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